

## **REMARKS**

### **I. Status of the Application**

Claims 1-50 were pending at the time of the Action. Claims 27-50 have been canceled as being drawn to a non-elected invention.

The drawings are objected to on page 2 of the Action. Claims 19, 20 and 24 are objected to because the Action takes the position that the terms "about" and "substantially" render the claims indefinite.

Claims 1-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,039,452 to McClane (McClane) in view of U.S. Patent No. 5,873,831 to Bernstein (Bernstein).

Claim 51 is new. Support for Claim 27 can be found, for example, on page 7, lines 18-21 of Applicants' specification.

Reconsideration of the above objections and rejections is respectfully requested in view of the remarks that follow.

### **II. Drawings**

The drawings are objected to under 37 C.F.R. 1.121(d). In response, replacement drawing sheets are submitted herewith. Applicants submit that the replacement drawings comply with 37 C.F.R. 1.121(d) and request that the drawing objections be withdrawn.

### **III. Claim Objections.**

The Action takes the position that the terms "about" and "substantially" render Claims 19, 20 and 25 indefinite. Applicants respectfully disagree.

The terms "about" and "substantially" and other terms of degree may satisfy the requirements of definiteness if "one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention." M.P.E.P. 2173.05(b). For example, In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. Another court held that the limitation "which produces substantially equal E and H plane illumination patterns" is

definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

Claim 19 recites that "the spatial representation comprises a map of a plurality of adjacent layers of the retina and covers a region about 2-5 mm wide." Claim 20 recites that "the spatial representation comprises at least about 1000 data pixels." Claim 24 recites that "the generating and illuminating steps are performed substantially simultaneously." Applicants submit that the use of the terms "about" and "substantially" in such claims are definite because one of skill in the art would clearly understand the scope of the invention.

Accordingly, Applicants request that the objections to Claims 19, 20 and 24 be withdrawn.

#### **IV. The 103 Rejections**

Independent Claim 1 recites a non-invasive *in vivo* method for assessing carotenoids in the retina and/or macula, including:

- performing Optical Coherence Tomography (OCT) on a retina of a subject; and
- generating a spatial representation of carotenoid levels in the retina based on data from the OCT of the retina.

The Action rejects Claims 1-26 as being unpatentable over McClane and Bernstein. McClane proposes Raman imaging of carotenoids and related chemical substances in macular pigments. The Action concedes that McClane does not use Optical Coherence Tomography (OCT) as recited in Claim 1. However, the Action takes the position that Bernstein discloses OCT in column 5, lines 25-37.

Applicants respectfully disagree with the Action's characterization of Bernstein and submit that Bernstein also does not disclose or render obvious using OCT, *e.g.*, for generating a spatial representation of carotenoid levels in the retina based on data from the OCT of the retina as recited in Claim 1.

Applicants submit that Bernstein merely proposes the use of monochromatic laser light for Raman spectroscopy and mentions using scanning techniques in this context in "a manner analogous ... to optical coherence tomography." Bernstein, col. 5, lines 25-37.

Bernstein does not disclose using optical coherence tomography (OCT), which generally requires the use of low coherence light.

In particular, Bernstein proposes using Raman spectroscopy and monochromatic laser light that is directed onto a material. The resulting Raman scattered light detected from the material can be used to locate, identify and quantitate concentrations of a material. For example, macular carotenoids can be measured in live subjects using Raman spectroscopy such that retinal exposure to low laser power (*i.e.*, monochromatic light) generates a usable macular carotenoid Raman signal without significant damage to the macular tissue.

Bernstein, col. 4, lines 15-56.

The portion of Bernstein cited in the Action states as follows:

It should be appreciated, however, that various delivery means for directing the generated light would be within the scope of the present invention. For example, one preferred delivery means for directing generated light is a slit lamp. Other preferred delivery means include, but are not limited to direct ophthalmoscopes and mirrors. Alternatively, the delivery means for directing generated light may incorporate a small beam scanned across the macular area in a manner analogous to the method used in scanning laser ophthalmoscope or optical coherence tomography, both of which should be familiar to those of skill in the art.

Bernstein, col. 5, lines 25-37. Accordingly, Bernstein proposes using a small beam scanned across the macular area; however, Applicants submit that all of the light sources mentioned in Bernstein are monochromatic, laser light sources used for Raman spectroscopy and not OCT.

In contrast to the laser light sources of Bernstein, OCT devices typically use a low coherent (*i.e.*, polychromatic) light source as discussed, for example, on page 7, lines 18-21 of Applicants' specification. Although certain dependent claims according to embodiments of the present invention recite transmitting blue and/or infrared light to the retina (*e.g.*, Claims 2-3), this excitation light can be transmitted with a low coherence light source, such as a superluminescent diode. Applicants' specification, page 3, lines 8-11. Accordingly, Applicants submit that the brief mention of beam scanning across the macular area apparently using monochromatic, laser light sources in Bernstein does not disclose OCT scanning as alleged in the Action on page 4.

Applicants further note that Bernstein apparently quantifies Raman spectral intensities as shown in the graphs of Figures 1, 2, 4A-4F and 5A-5B. However, Bernstein does not appear to discuss imaging or other spatial representations of carotenoid levels.

For at least these reasons, Bernstein does not disclose or render obvious generating a spatial representation of carotenoid levels in the retina based on data from the OCT of the retina as recited in Claim 1. This recitation is also not disclosed in McClane, which the Action concedes does not disclose OCT. Applicants further note that the light source of McClane is also a monochromatic light source, such as a low power solid state or argon ion laser. *See* McClane, col. 5, lines 31-34.

Accordingly, the cited references do not disclose or render obvious the recitations of Claim 1, and therefore, Claim 1 is patentable over the cited art. Claims 2-26 depend from Claim 1 and are patentable at least per the patentability of Claim 1. Accordingly, Applicants request that the rejections of such claims be withdrawn.

In addition, at least certain dependent claims are separately patentable for at least the reasons that follow.

**V. Claim 5 is Separately Patentable**

Claim 5 depends from Claim 1 and is patentable at least per the patentability of Claim 1 discussed above. In addition, Claim 5 recites that "the performing step comprises transmitting a low coherence light with a superluminescent diode." As noted above, the use of low coherence light is not disclosed by the Raman scattering techniques and laser light sources in either McCand or Bernstein.

Accordingly, Claim 5 is separately patentable and Applicants request that the rejection of Claim 5 under 35 U.S.C. 103(a) be withdrawn.

**VI. Claim 51 is Separately Patentable**

Claim 51 depends from Claim 1 and is patentable at least per the patentability of Claim 1 discussed above. In addition, Claim 51 recites that "the performing step comprises transmitting a low coherence light to a portion of the retina." As noted above, the use of low coherence light is not disclosed by the Raman scattering techniques and laser light sources in either McCand or Bernstein.

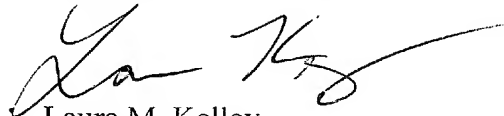
In re: Lambert, et al.  
Application No.: 10/773,099  
Filed: February 5, 2004  
Page 10 of 10

Accordingly, Claim 51 is separately patentable and Applicants request an indication of same.

### CONCLUSION

Accordingly, Applicants submit that the present application is in condition for allowance and the same is earnestly solicited.

Respectfully submitted,

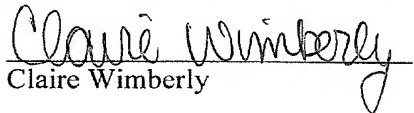


Laura M. Kelley  
Registration No. 48,441

**USPTO Customer No. 20792**  
Myers Bigel Sibley & Sajovec  
Post Office Box 37428  
Raleigh, NC 27627  
Telephone (919) 854-1400  
Facsimile (919) 854-1401

### CERTIFICATION OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on February 18, 2008.

  
\_\_\_\_\_  
Claire Wimberly